REMARKS

Claims 1-5 and 7-24 are pending in the application and are presented for the Examiner's review and consideration. In this Response, claims 1, 15 and 23 have been amended; and claim 24 has been added. Applicants believe that the claim amendments, cancellations, and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that they do not limit the range of any permissible equivalents.

§102 Rejection

Claims 1-5, 7-9 and 11-23 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,848,979 to Bonutti ("the '979 patent").

For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Initially, Applicant notes that the '979 patent was published on December 15, 1998, and the instant application claims priority ultimately to application serial number 09/088,134, filed June 1, 1998. As the effective file date is prior to the publication date of the '979 patent, Applicant respectfully submits that 35 U.S.C. §102(b) would not appear to be applicable. Notwithstanding this, to further prosecution, Applicant addresses the '979 patent in this response.

The '979 Patent

The '979 patent discloses an orthosis operable to vary the extent of supination or pronation of a hand connected with an arm of a patient as well as other joints. (Abstract). Viscoelastic body tissue connecting the proximal end portions 92 and 96 (FIG. 2) of the radius and ulna 84 and 86 with the humerus 100 in the arm 66 of a patient may require stretching to enable the hand 68 of

the patient to move through a desired range of motion in supination and/or pronation. (Col. 10, lns. 11-16).

...the main drive assembly 34 is operable to rotate the lower cuff 32 and the gripped portion of the wrist and hand of the patient about an axis 36. (Col. 2, lns. 49-52). To effect pronation of the hand 68 from the initial orientation of FIGS. 3 and 4 to a palm downward orientation shown in FIGS. 5 and 6, the knob 60 of the main drive assembly 34 is rotated in a counterclockwise direction (as viewed in FIG. 3). (Col. 10, lns. 58-62).

The main drive assembly 34 (FIG. 3) rotates the lower cuff 32 about the axis 36 which extends through the wrist 74 and elbow 78 of the arm 66 of the patient. (Col. 8, lns. 30-33). The axis 36 extends generally parallel to and is at least reasonably close to being coincident with the longitudinal central axis of the lower portion 76 of the arm 66. (Id). The axis 36 extends along the radius and ulna 84 and 86 (FIG. 2). (Id).

The main drive assembly 34 is connected with the lower cuff arm 24 and is operable to rotate the lower cuff 32 about the axis 36. (Col. 8, lns. 44-46). The lower cuff 32 extends through the central opening 52 (FIG. 9) in the main gear 48. (Id).

Until the main drive assembly 34 is actuated, the lower portion 76 and the upper portion 80 of the patient's arm 66 are held against movement relative to each other. (Col. 10, lns. 49-57). Thus, the lower portion 76 of the arm 66 (FIG. 3) is held against movement relative to the lower cuff arm 24 by the lower cuff 32. (Id). The upper portion 80 of the arm 66 is held against movement relative to the upper cuff arm 26 by the upper cuff 42. At this time, the only way to move the arm 66 is at the shoulder 70. (Id).

As such, the '979 patent discloses a device for stretching the viscoelastic tissue connecting the radius and ulna to the distal end of the humerus. The device has an arcuate gear having an axis extending along the radius and ulna, with an opening into which the hand is passed. The hand is secured to a cuff which rotates with the gear. As the gear is turned, the hand turns, rotating the radius and ulna relative to the distal end of the humerus.

In contrast, in the present invention, a shoulder orthosis 10 is used to correct misalignment or malfunction of joints in a shoulder 16 of a patient. (¶[0017]). The shoulder orthosis 10 includes a base section 30 (FIGS. 1-3) which is connected with a trunk 32 (FIG. 1) of the patient's body. (¶[0018]). The shoulder orthosis 10 includes an upper arm section 38 (FIGS. 1-3) which is connected with the upper arm section 40 (FIG. 1) of the left arm 20 of the patient. (¶[0019]). A lower arm section 42 (FIGS. 1-3) of the shoulder orthosis 10 is connected with a lower arm section 44 (FIG. 1) of the left arm 20 and a hand 46 of the patient 14. (Id).

The main drive assembly 50 is operable to rotate bones in the arm 20 of the patient 14 relative to the shoulder 16 of the patient. (¶[0020]). Operation of the main drive assembly 50 rotates the bones in the arm 20 of the patient 14 about a longitudinal central axis of the upper arm section 40. (Id). The main drive assembly 50 can be operated in any one of two directions to effect either internal or external rotation of a humerus bone in upper arm section 40 relative to the shoulder 16. (Id).

To effect stretching of the viscoelastic body tissue interconnecting the upper arm section 40 and shoulder 16, the main drive assembly 50 is operated to rotate the humerus bone 62 (FIG. 4) in the upper arm section 40 relative to the shoulder 16. (¶[0024]).

The secondary drive assembly 58 (FIG. 1) moves the upper arm section 40 and the lower arm section 44 of the arm 20 of the patient 14 relative to the shoulder 16. (¶[0058]). The secondary drive assembly 58 is operated to align the central axis of the humerus bone 62 (FIG. 4) in the upper arm section 40 with the center of the glenoid cavity 80 in the scapula bone 82. (Id).

When the central axis of the humerus bone extends through a central portion of the glenoid cavity 80, the humerus bone 62 can be rotated about its central axis while the scapula bone 82 and clavicle bone 84 remain substantially stationary relative to the trunk 32 of the patient 14. (¶[0059]). This is because when the humerus bone 62 is aligned with the center of the glenoid cavity 80, the central axis of the humerus bone 62 extends through a center of curvature of an arcuate surface 92 on the head end portion 68 of the humerus bone 62 and through a center of curvature of an arcuate surface 94 of the glenoid cavity 80. (Id).

It should be understood that the main drive assembly 50 is not operated to rotate the humerus bone 62 until after the secondary drive assembly 58 has been operated to position the humerus bone in alignment with the glenoid cavity 80. (¶[0072]).

Furthermore, it is contemplated that the main gear 240 could be offset to one side, for example, downward, of the elbow 54 and rotatably connected with the upper cuff arm 150. (¶[0074]). If this was done, the arm 20 of the patient 14 would not extend through the main gear 240 and the opening 244 could be eliminated. (Id).

The central axis of the main gear 240 extends parallel to the longitudinal central axis of the upper cuff arm 150 and is coincident with a longitudinal central axis of the upper section 40 (FIG. 1) of the arm 20 of the patient. (¶[0075]).

As such, the present invention discloses a shoulder orthosis for stretching tissues in the shoulder joint. A main drive rotates the humerus relative to the shoulder. Prior to rotating the humerus, the proximal end of the humerus is aligned relative to the glenoid cavity, using a secondary drive attached between a base section and an upper arm section. This enables the scapula and clavicle to remain stationary, as the tissue in the shoulder joint is stretched.

Claim 1 recites, a shoulder orthosis device for effecting rotational movement of a lower arm portion of a patient's arm about a central longitudinal axis of a humerus bone of an upper arm portion of the patient's arm, comprising: a lower arm section configured for receiving the lower arm portion, the lower arm section configured, dimensioned, and arranged for maintaining the lower arm portion substantially orthogonal to the upper arm portion; and a drive member operably connected to the lower arm section proximate the elbow and including a gear connected to the lower arm section having an axis substantially aligned with the central longitudinal axis of the humerus and manually operable by the patient to rotate the lower arm portion about the central longitudinal axis of the humerus bone such that the lower arm portion is maintained substantially orthogonal to the upper arm portion, whereby during at least a portion of the rotation of said gear, the humerus is rotated, through its connection with the lower arm portion of

a patient's arm, about its longitudinal axis, and body tissue in the shoulder joint is thereby stretched.

Independent claims 15 and 23 have analogous recitations. Claim 15 further recites, *inter alia*, means associated with the manually operated drive member operative to maintain a position of said gear when operation of said manually operated drive member is interrupted.

Claim 23 further recites, *inter alia,* means associated with the manually operated drive member operative to reverse the direction of rotation of said gear, and means connected to said upper arm section operative to align the upper arm portion with a glenoid cavity of a shoulder joint.

Accordingly, Applicant respectfully submits that claims 1, 15 and 23 are patentable over the '979 patent. As claims 2-5, 7-9, and 11-14 depend from claim 1, and claims 16-22 depend from claim 15, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited reference for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 102 rejection.

§103 Rejection

Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Bonutti '979. As described above, Applicant submits that claim 1 is patentable over the cited reference. As claim 10 depends from claim 1, this dependent claim necessarily includes all the elements of its base claim. Accordingly, Applicant respectfully submits that claim 10 is allowable over the cited reference for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 103 rejection.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed due. However, please charge any additional fees (or credit any overpayment of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A04-006-3).

Respectfully submitted,

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